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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/720,136 | 03/16/2001 | Beverly B. Teter | UMARY3 | 7554 |
| 7590 | 03/31/2008 | | EXAMINER | |
| Peter J. Batch III, Esq. Synnestvedt Lechner & Woodbridge LLP P.O. Box 592 Princeton, NJ 08542-0592 | | | OGUNBIYI, OLUWATOSIN A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 09/720,136 | Applicant(s) TERER, BEVERLY B. |
| | Examiner OLUWATOSIN OGUNBIYI | Art Unit 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 02 January 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-18,25,26,38,45 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-18,25,26,38,45 and 51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

RESPONSE TO AMENDMENT

The amendment filed 1/2/08 has been entered into the record. Claims 1-9, 19-24, 27-37,39-44 and 46-50 have been cancelled. Claims 10-18,25,26,38,45 and 51 are pending. Claims 10-18,25,26,38,45 and 51 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Objections/Rejections Withdrawn

The objection to claims 14, 25, 26 and 51 is withdrawn in view of the amendment to claim 14.

The rejection of claims 14,25,26 and 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn in view of the amendment to claim 14.

The rejection of claims 14,25,26 and 51 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claim 14.

Rejections Maintained

The rejection of claim 13 under 35 U.S.C. 112, second paragraph is maintained for reasons made of record in the last office action filed 7/2/07.

The rejection of claims 10-13, 18, 38 and 45 under 35 U.S.C. 102(b) as being anticipated by Schroeder et al. US 4,169,041, July 3, 1979 is maintained for reasons made of record in the last office action filed 7/2/07.

Applicant argues that Schroeder et al does not disclose or suggest an animal feed composition which includes crude protein and an antibiotic supplement wherein all or a portion of the antibiotic supplement is replaced with an anti-bacterial amount of an anti-microbial fatty acid component, wherein the anti-microbial fatty acid component is a high lauric acid natural oil or a derivative thereof.

Applicants further argue that Schroeder et al never disclosed or suggest combining a natural oil high in lauric acid with crude protein and that palm oil is not high in palmitic acid not lauric acid and that coconut oil and antibiotics are only mentioned once in Schroeder and not in combination with crude protein.

Applicant's arguments are carefully considered but not found persuasive. Schroeder et al does disclose an animal feed composition comprising crude protein, antibiotic and a high lauric acid natural oil as set forth in p. 7-9 of the last office action filed 7/2/07. Schroeder et al teaches components of an animal feed composition (see table 1 column 2 and columns 3 to column 10, for more detailed description of components of said animal feed composition) which can comprise crude protein (column 7 under The Protein Ingredient), antibiotic (column 7 under miscellaneous ingredients) and coconut oil (natural oil high in lauric acid, a suitable oil for said animal feed composition, see column 5 under The Fat Ingredient especially line 61) irrespective of whether Schroeder mentions antibiotic and coconut oil only once.

The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006,1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v.Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied,493 U.S. 975 (1989). Further, disclosed examples and preferred embodiments do not constitute a teaching away from a broader

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disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ423 (CCPA 1971). Also See MPEP 2123.

The rejection of claims 10-14, 15-18, 25, 26, 38, 45 and 51 under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of 21 CFR section 558.15 1997 (New animal drugs for use in animal feeds – antibiotic, nitrofurantoin and sulfonamide drugs in the feed of animals) and J. Raloff, 1998, Science News vol. 154 p. 39) is maintained for reasons made of record in the previous office action filed 7/2/07.

Applicant argues that the J. Raloff reference is not prior art because the present application claims priority to the provisional application 60/090303 filed June 23, 1998 and that J. Raloff is dated July 18, 1998.

Applicants' argument is carefully considered but is not found persuasive. J. Raloff, is appropriate prior art as applied because the instant animal feed composition as set forth in claims 10-18, 25, 26, 38, 45 and 51 is not disclosed in the provisional application 60/090303 and thus the claims do not meet the requirements of 35 U.S.C 112 first paragraph for priority to the provisional application 60/090303.

Applicant can best resolve this issue by pointing by page number and line number where the instantly claimed animal feed composition as claimed in claims 10-18, 25, 26, 38, 45 and 51 is disclosed in the provisional application as filed.

Thus, the combination of Schroeder et al and 21 C.F.R. section 558.15 and J. Raloff is obvious over the instant claims as set forth in the last office action (7/2/07) and said combination teaches an animal feed composition comprising a natural oil high in lauric acid and crude protein and less than 50% of an antibiotic supplement.

New Rejections

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, wherein the anti-microbial fatty acid component is a high lauric acid natural oil, having a high lauric acid content, wherein the high lauric acid oil is high lauric acid soy oil.

The nature of the invention and scope of claim 11 is the use of high lauric acid soy oil in an animal feed composition as set forth above.

The instant specification teach on p. 3 line 24 teaches that soybean oil derived from plants that have been genetically modified to have a high lauric acid content can be used in the instant invention. However, the instant specification as filed does not teach soy oil from a soy plant that has been genetically modified to have high lauric acid content. The specification is devoid of any guidance as to how to make a genetically modified soybean plant that is high in lauric acid content. Soy oil has no detectable amounts of lauric acid as evidenced by Yabuuchi et al (Animal Science Journal, 77:300-307, 2006).

Voelker et al around the time of filing of the instant specification (The Plant Journal, 1996, 9:229-241) teaches how to make transgenic rapeseed/canola with high lauric acid content. However, the art as of the time the instant invention was made is silent as to soy oil having a high lauric acid content and the instant specification does not teach an example of such a oil or how to make such an oil.

Thus, undue experimentation would be required of one skilled in the art to make and use the instant animal feed composition because the instant specification has not taught, as of the filing date, how to make soy oil with high lauric acid content.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of Williams et al. US 5,378,477, Jan. 3, 1995.

The claims are drawn to "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-microbial fatty acid component, wherein the anti-microbial fatty acid component is a high lauric acid natural oil, having a high lauric acid content, wherein the high lauric acid oil is palm kernel oil

Schroeder et al teach a composition of an animal feed supplement (see comprising crude protein (e.g. blood, rabbit pellets, dried chicken manure etc, column 7 lines 21-39, table 4) and antibiotic (column 7 line 67) and high lauric acid natural oil such as coconut oil (column 5 lines 50-54 and lines 60-62). Schroeder et al teaches that animal feed compositions comprise a fat ingredient as a source of animal edible such edible water insoluble fats and oils from animal and vegetable sources.

Schroeder et al does not teach an edible vegetable oil such as palm kernel oil.

Williams et al teach palm kernel oil in an animal feed composition which results in desirable increase in daily feeding frequency and total daily feed consumption (column 8 example 3 to column 9 lines 12-16 and claims 1-8).

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to substitute the coconut oil of Schroeder et al with palm kernel oil as taught by Schroeder et al and Williams et al because Williams et al teach palm kernel oil in an animal feed composition which results in desirable increase in daily feeding frequency and total daily feed consumption and Schroeder et al teach that that animal feed compositions comprise a fat ingredient as a source of animal edible fat e.g. edible water insoluble fats and oils from a vegetable source and

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 and Williams et al. US 5,378,477, Jan. 3, 1995 as applied to claims 10 and 11 above further in view of the publication: Biotechnology Consultation Memorandum of Video-Conference BNF NO. 000025, April 4, 1995 (<http://www.cfsan.fda.gov/~rdb/bnfm025.html>).

The combination of Schroeder and Williams as set forth *supra* does not teach a high lauric acid rapeseed oil.

The BNF NO. 000025 publication teaches a rapeseed oil with high lauric acid content obtained from transgenic rapeseed. The publication teaches that said high lauric acid rapeseed oil is not materially altered in any respect relevant for animal feed and suggests said oil as a replacement for palm kernel oil.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to substitute the palm kernel oil in the composition of Schroeder and Williams as set forth *supra* with a reasonable expectation of success because BNF NO. 000025 publication suggests that rapeseed oil with high lauric acid content can be used to replace palm kernel oil and that said rapeseed oil is not materially altered in any respect relevant for animal feed.

Status of Claims

Claims 10-18, 25,26,38,45 and 51 are rejected. No claims allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645

